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EXAMINER

CHORBAJI, MONZER R

ART UNIT PAPER NUMBER

1744

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,786

Applicant(s)

ROBITAILLE ET AL.

Examiner

MONZER R. CHORBAJI

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-35 is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 12/12/2005

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlson (U.S.P.N. 5,069,880) in view of Carman et al (U.S.P.N. 6,284,193) and further in view of Jacobs et al (U.S.P.N. 6,325,972).

With respect to claim 1, the Karlson reference teaches the following: providing a sterilization chamber (figure 8:A), placing articles into the chamber (col.8, lines 15-16), applying a vacuum of 1 mm pressure (col.8, lines 19-2, 1mm is equivalent to 1.33 mbar) to the sterilization chamber such that as taught in the specification on page 6, paragraphs 00018-00019, a vacuum pressure of 1.33 mbar falls within the disclosed range that inherently results in lowering the boiling point of water within the chamber to a temperature below the temperature of the sterilization chamber, supplying humidified ozone-containing gas (col.8, lines 22-26) where the preselected level is the inherent full capacity for ozone by the sterilization chamber, stopping the supply of the ozone gas and sealing the chamber (col.8, lines 15-29, where the I valve and the II valve are closed and then the F valve is opened for the ozone to enter the chamber), which inherently results in maintaining the pressure level, the humidity level and the ozone gas level and releasing the vacuum in the sterilization chamber (col.8, lines 29-30). The Karlson reference fails to teach the following: separately supplying water and performing temperature equalization of the items and the atmosphere within the chamber. The Carman reference teaches separately supplying water to humidify the atmosphere close to saturation point within the chamber (col.7, lines 56-58 and line 12). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to additionally include a separate water humidifying step in the

Karlson process since depending on the length of sterilization cycle, longer duration cycles removes humidity creating the need for more humidity in the chamber (Carmen et al, col.4, lines 23-26).

However, the Carmen reference fails to teach performing temperature equalization of the items and the atmosphere within the chamber. The Jacobs reference, which is in the art of sterilizing medical articles by vaporizing sterilants, teaches drawing a vacuum then introducing fresh air (col.9, lines 61-67 and col.10, lines 1-2) into the chamber prior to adjusting the pressure in the sterilization chamber (col.10, lines 4-6 and line 11-13) to the sterilization pressure such that intrinsically preventing condensation. The specification on page 7 teaches that equalization is applying vacuum then injecting air just as shown in the Jacobs reference. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Karlson reference by adding an equalization step as taught by the Jacobs reference in order to raise the pressure within the chamber back to atmosphere (col.9, line 67 and col.10, lines 1-2).

With respect to claim 2, both the Karlson reference and the Carman reference fail to disclose equalizing the temperature of the articles and the chamber atmosphere and any components and materials in contact with the atmosphere; however, the Jacobs reference, which is in the art of sterilizing medical articles by vaporizing sterilants, teaches drawing a vacuum then introducing fresh air (col.9, lines 61-67 and col.10, lines 1-2) into the chamber. The specification on page 7 defines equalization as applying vacuum then injecting air resulting in the chamber, the articles and the atmosphere in

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the chamber all being at the same temperature. The vacuuming and the admission of air in the Jacobs reference is intrinsically capable of the chamber, the articles and the atmosphere in the chamber all being in the same temperature. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Karlson reference by adding an equalization step as taught by the Jacobs reference in order to raise the pressure within the chamber back to atmosphere (col.10, lines col.9, line 67 and col.10, lines 1-2).

With respect to claims 5-8 and 11, the Karlson reference teaches the following: applying a vacuum of 1 mm pressure (col.8, lines 19-2, 1mm is equivalent to 1.33 mbar), the level of humidity in the chamber is between 85 to 100% (col.8, lines 5-8) and passing all gases evacuated from the chamber through a means for destroying ozone (figure 8, W).

With respect to claims 3-4, the Karlson reference fails to teach temperature range values within the chamber. The Carman reference teaches the following: chamber temperature of 25 degree Celsius (col.7, lines 24-25 such that 80 degrees Fahrenheit is equal to 27 degree Celsius). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to additionally include a temperature monitoring means for the Karlson process since some items are temperature sensitive that require maintaining the conditions within the chamber under relatively cool conditions (Carmen et al, col.7, lines 22-25).

5. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlson (U.S.P.N. 5,069,880) in view of Carman et al (U.S.P.N. 6,284,193), Jacobs et al

(U.S.P.N. 6,325,972) as applied to claim 1 and further in view of Shapiro (U.S.P.N. 3,719,017).

With respect to claims 9-10, the Karlson reference teaches stopping the supply of the ozone gas and sealing the chamber (col.8, lines 15-29, where the I valve and the II valve are closed and then the F valve is opened for the ozone to enter the chamber), which inherently results in maintaining the pressure level, the humidity level and the ozone gas level; however, the Karlson reference, the Carman reference and the Jacobs reference all fail to teach repeating the following steps: applying a vacuum, humidifying, supplying ozone-containing gas, stopping the supply of the ozone gas and sealing the chamber. The Shapiro reference, which is in the art of sterilizing packaging devices by using ozone, teaches repeating the exhausting (vacuuming) and refilling of the container with ozone mist (col.2, lines 11-15 and col.4, lines 61-64). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Karlson reference by repeating the steps of vacuuming, humidifying, supplying ozone, stopping the supply of the ozone gas and sealing the chamber in order to completely expel air from the container and surround the article therein with the sterilizing medium as taught by the Shapiro reference (col.2, lines 11-15).

6. Claims 12-13 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Jacobs et al (U.S.P.N. 6,325,972).

With respect to claim 12, the Carman reference teaches an apparatus (col.1, lines 9-12) using ozone-containing gas (col.2, lines 25-30) to sterilize medical articles including the following: a sterilization chamber (figure 2:1), means for applying vacuum (figure 2:5), means for applying ozone gas to the chamber (figure 2:6 and 10), means for supplying water vapor to the chamber (figure 2:12) and means for selectively interrupting the supplying of water vapor and ozone gas (figure 2:valve 4 and valve 10 and valve 2) such that the valves are capable of being closed to seal the chamber. However, the Carman reference fails to teach air inlet means. The Jacobs reference, which is in the art of sterilizing medical articles by vaporizing sterilants, teaches drawing a vacuum then introducing fresh air (col.9, lines 61-67 and col.10, lines 1-2) into the chamber prior to adjusting the pressure in the sterilization chamber (col.10, lines 4-6 and line 11-13) to the sterilization pressure such that intrinsically preventing condensation. The specification on page 7 teaches that equalization is applying vacuum then injecting air just as shown in the Jacobs reference. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Carman reference by adding means for equalizing the temperature of the articles and the atmosphere within the chamber as taught by the Jacobs reference in order to raise the pressure within the chamber back to atmosphere (col.9, line 67 and col.10, lines 1-2).

With respect to claims 13 and 15-22, the Carman reference teaches the following: vacuum within the chamber is maintained for a preselected time interval (col.7, lines 64-67 and col.8, line 1) such that the vacuum (col.7, lines 54-55) is adjusted

to any desired value within the disclosed range (col.7, lines 54-56), a door for sealing the chamber (col.7, lines 28-32), an ozone generator (6), a pump (5) that generates vacuum range that includes 55.3 mbar and higher (col.7, line 55), an inherent means for controlling the concentration of ozone in order to maintain such a concentration (col.4, lines 36-41) and adjusting the vacuum pressure (col.7, lines 42-44 including a value for maintaining vacuum).

With respect to claim 23, the Carman reference teaches that all parameters of the sterilization process are controlled by a programmable industrial process controller (8). This teaching intrinsically includes feedback mechanisms, for example, based on readings from ozone level and vacuum pressure values within the chamber (col.4, lines 36-39 and col.7, lines 52-56).

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Jacobs et al (U.S.P.N. 6,325,972) as applied to claim 12 and further in view of Shapiro (U.S.P.N. 3,719,017).

With respect to claim 14, the Carman reference teaches the following: a chamber door (figure 2:2), a humidifier (figure 2:12), means for controlling the chamber temperature (figure 2:11), means for controlling the door (col.1, lines 29-31) and means for controlling the humidifier (the reference must intrinsically include some humidity control means in order to introduce and stop the introduction of humidity into the chamber); however, both the Carman reference and the Jacobs reference fail to teach the use of a water reservoir. The Shapiro reference, which is in the art of sterilizing packaging devices by using ozone, teaches that the source of water vapor is from water

reservoir (figure 2:WR). The specification on page 27 does not provide any benefits for using a water reservoir. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Carman reference by substituting water vapor source for water reservoir as evidenced by the Shapiro reference (figure 2:WR).

Allowable Subject Matter

8. Claims 24-35 are allowed.

Response to Arguments

9. Applicant's arguments filed on 12/12/2005 have been fully considered but they are not persuasive.

On pages 12-14 of the Remarks section, applicant argues that the Carmen reference sterilizes articles with gaseous ozone through a continuous process not a batch process as the instant claims stand. Now, the Karlson reference is applied to show that sterilizing items with gaseous ozone by using the static method is known.

On page 14 of the Remarks section, applicant argues that, "However, Jacobs et al do neither teach nor even acknowledges anywhere that removing water from the surface of an object by evaporation under vacuum will result in localized cooling of the object." The examiner disagrees. The Jacobs reference teaches drawing a vacuum then introducing fresh air (col.9, lines 61-67 and col.10, lines 1-2) into the chamber prior to adjusting the pressure in the sterilization chamber (col.10, lines 4-6 and line 11-13). These steps will inherently just like as explained in the specification on page 7 would result in removing water from surfaces of items by evaporation under vacuum leading to

a localized cooling of the items. See specification, page 7 where equalization is applying vacuum then injecting air just as shown in the Jacobs reference.

On page 15 of the Remarks section, applicant argues that, "Thus, Jacobs et al not only fail to teach to the art skilled person the reason and need for the temperature equalization step of the present invention, but teach a sterilization totally opposite goals from the process of the present invention." The examiner disagrees since the combination of Karlson and Jacobs is only for the equalization step and not for the way sterilization is performed. Clearly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Karlson reference by adding an equalization step as taught by the Jacobs reference in order to raise the pressure within the chamber back to atmosphere (col.9, line 67 and col.10, lines 1-2).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji
Patent Examiner
AU 1744
03/06/2006



GLADYS J.P. CORCORAN
PRIMARY EXAMINER